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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,254	04/09/2004	Shahriar Shane Taremi	JB06017US01	1701

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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KENILWORTH, NJ 07033-0530

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/822,254

Applicant(s)

TAREMI ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007 and 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,14,15,28,30,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1,2,15,28,30,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/07 and 12/19/06 has been entered.
- [2] Claims 1-2, 14-15, 28, 30, and 34-35 are pending in the application.
- [3] Applicant's amendments to the claims, filed on 1/24/07, are acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [4] Applicant's arguments filed on 12/19/06 and 1/24/07 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

- [6] The specification discloses a compound referred to as "SCH549128." See, e.g., p. 6, line 16 and p. 45, line 30. However, it is unclear as to the structure of the compound identified as "SCH549128." As such, the specification is objected to as being

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unclear in the compound that is represented by the name "SCH549128." It is suggested that applicant clarify the compound that is referred to as "SCH549128."

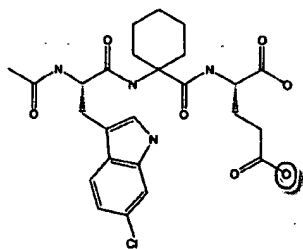
Claim Objections

[7] Claims 1, 14, and 28 are objected to as the oxygens of the carboxy groups of the claimed or recited compounds do not have proper valency. For example, a skilled artisan would recognize the oxygens of the carboxy groups should have either a negative charge or a bonded hydrogen.

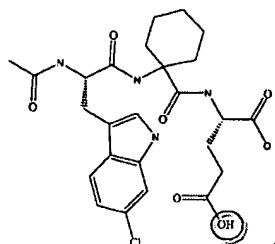
Claim Rejections - 35 USC § 112, Second Paragraph

[8] Claims 28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the specification, the compound $\text{Ac-}^{6\text{Cl}}\text{WAC}_{3\text{C}}\text{E}$ has the formula (circle added for emphasis):



However, claims 28 and 30 also identify a compound as $\text{Ac-}^{6\text{Cl}}\text{WAC}_{3\text{C}}\text{E}$, which has a different formula as shown below (circle added for emphasis):



The claims are rejected in view of the discrepancy of the structures identified as Ac-^{6Cl}WAC_{3C}E in the claims and the specification. It is suggested that applicant clarify the meaning of the claims.

Claim Rejections - 35 USC § 112, First Paragraph

[9] The new matter rejection of claim(s) 1-2 and 15 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in the prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the examiner is applying an overly narrow and literal interpretation of the claims and that the specification's example 2 disclosing a 34 mg/mL concentration of HDM2(F55Y/Y76H) would not be limited to this single species, but is intended to apply to all disclosed polypeptides. According to applicant, one of skill in the art would appreciate that other disclosed polypeptides would also be soluble at this concentration.

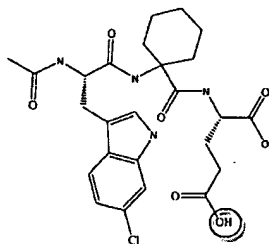
Applicants' argument is not found persuasive. In this case, the issue is not one of whether other disclosed polypeptides would have the ability to solubilize at the recited concentration. Instead, the issue is one of new matter, specifically, whether the

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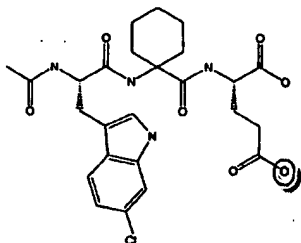
application as originally filed provides support for the added concentration limitation.

MPEP § 2163 states that “there is no *in haec verba* requirement” for newly added claim limitations, only that “newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” According to the same section of the MPEP, “[t]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 156364, 19 USPQ2d at 1117.” In view of the disclosure, there is no dispute that the original application supports HDM2(F55Y/Y76H) protein-tripeptide complex solubilized to 34 mg/ml in 25 mM Hepes-potassium hydroxide, pH7.5, 0.15 M potassium chloride, 1 mM EDTA, 0.03% sodium azide and 5 mM DTT buffer as disclosed in the specification beginning at p. 45, middle. However, this disclosure of a protein complex fails to support any purified polypeptide as encompassed by the claims, particularly as there is no express, implicit, or inherent support for this limitation applying to all of the recited proteins in claims 1 and 15. While applicant takes the position that the Example 2 disclosure is intended to apply to all disclosed proteins, there is no indication in the specification that the Example 2 protein complex concentration is intended to apply to any and all of the proteins as disclosed in the specification. Consequently, the Example 2 disclosure fails to provide adequate support for the concentration limitation of the claims. Applicant is invited to show support in accordance with MPEP 2163 for the concentration limitation as recited in the claims.

Claims 28 (claim 34 dependent therefrom) and 30 (claim 35 dependent therefrom) recite a compound, wherein the compound is identified as Ac-⁶ClWAC_{3C}E and is shown below (circle added for emphasis):



However, while the examiner can find support for the compound identified as Ac-⁶ClWAC₃C and shown at p. 38 of the specification as shown below (circle added for emphasis):



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the examiner can find no support for the compound of claims 28 and 30 in the original application as filed. Applicant is invited to show support for the compound as recited in claims 28 and 30.

[11] Claims 1-2, 15, 28, 30, and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Initially, it is noted that claims 1-2 and 15 were rejected under 35 U.S.C. 112, first paragraph, for lack of adequate written description in the Office action mailed on 8/26/05 (see paragraph 17 beginning at p. 6) and was subsequently withdrawn in the Office action mailed on 8/8/06. However, upon further consideration, claims 1-2 and 15 are rejected herein for reasons that follow.

MPEP 2111.01 states, "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." Indeed, applicant acknowledges that "the specification was intended to be interpreted broadly and liberally with respect to the scope of the invention" (response filed on 12/19/06 at p. 9, top). Although not expressly stated or required in the claims, the "purified polypeptide" of claims 1-2 and the "polypeptide-compound complex" of claim 15 have been interpreted as encompassing a genus of proteins in crystalline form (claims 1-2) or a genus of polypeptide-compound

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complexes in crystalline form, particularly as the instant application is directed to proteins in crystalline form.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Regarding claims 1-2 and 15 to the extent the claims encompass crystalline polypeptides and complexes thereof, the specification fails to disclose only a single representative species of the genus of claimed crystals, i.e., a crystal of SEQ ID NO:6 (Hdm2 Y76H) co-crystallized with Ac-⁶⁰WAC_{3C}E having the unit cell dimensions and space group symmetry as set forth at p. 63 of the specification. While it is noted that the specification discloses a crystal of SEQ ID NO:10 (Hdm2 F55Y/Y76H) co-crystallized with "SCH549128" (see particularly specification at pp. 45-46), the specification fails to disclose the structure of the compound identified as "SCH549128" such that a skilled artisan would recognize that applicant was in possession of this compound at the time of the invention. Thus,

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other than the single noted representative species, the specification fails to disclose the structures of any other members of the claimed genus, which encompasses crystals having any unit cell dimensions and space group symmetries. While it is noted that the crystal of claim 30 recites space group and unit cell dimensions, this claim encompass a genus of crystals of polypeptides "having the amino acid sequence...", wherein "having" has been interpreted as being inclusive and open-ended and thus encompasses crystals of SEQ ID NO:6 comprising any additional amino acid sequence at the N- and/or C-termini. While applicant may argue that crystals of polypeptides having additional N- and/or C-terminal sequence would be expected to have the same space group and unit cell dimensions, there is no way to predict *a priori* the space group and unit cell dimensions of a protein, as evidenced by the references of Kierzek et al. (cited in the Office action mailed on 8/8/06; see cited relevant teachings) and Buts et al. (cited in the Office action mailed on 8/8/06; see cited relevant teachings) teach that the conditions required for protein crystallization cannot be predicted *a priori* and even a single amino acid mutation can alter the space group symmetry and unit cell dimensions of a crystallized protein.

Given the lack of description of a representative number of polypeptides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

RESPONSE TO ARGUMENT: Addressing the crystal of claims 28 and 30, applicant argues the rejection is obviated in view of the amendment to recite a specific polypeptide, space group and unit cell dimensions of the claimed crystal. However, at least for the reasons noted above, the crystals of claims 28 and 30 are not adequately described by the specification such that a skilled artisan would recognize that applicant was in possession of the claimed invention at the time of filing.

[12] Claims 1-2 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *soluble* purified polypeptide or complex thereof as encompassed by claims 1-2 and 15, does not reasonably provide enablement for protein crystals as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation is required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on

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the content of the disclosure. See MPEP § 2164.01(a). MPEP 2164.04 states, “[w]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection” and that “[t]he language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.” Accordingly, the Factors most relevant to the instant rejection are addressed in detail below.

Breadth of the claims: As noted above, MPEP 2111.01 states, “[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow.” Indeed, applicant acknowledges that “the specification was intended to be interpreted broadly and liberally with respect to the scope of the invention” (response filed on 12/19/06 at p. 9, top). Although not expressly stated or required in the claims, the “purified polypeptide” of claims 1-2 and the “polypeptide-compound complex” of claim 15 have been interpreted as encompassing a genus of proteins in crystalline form (claims 1-2) or a genus of polypeptide-compound complexes in crystalline form, particularly as the instant application is directed to proteins in crystalline form. The scope of crystalline polypeptides and complexes thereof as encompassed by claims 1-2 and 15 have any space group symmetry and any unit cell dimension. The scope of the claim is not commensurate in scope with the enablement provided by the specification. In this case,

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the specification is enabling only for a *soluble* purified polypeptide or complex thereof as encompassed by claims 1-2 and 15.

The state of the prior art; The level of one of ordinary skill; The level of predictability in

the art: The state of the art at the time of the invention acknowledges a high level of unpredictability for making the full scope of claimed crystals. For example, the reference of Branden et al. ("Introduction to Protein Structure Second Edition", Garland Publishing Inc., New York, 1999; cited in the Office action mailed on 8/26/05) teaches that "[c]rystallization is usually quite difficult to achieve" (p. 375). In view of the use of the claimed crystal for generating a three-dimensional structure, it is noted that the claimed crystals should be of diffraction quality, having a well-ordered structure. Branden et al. teaches that "[w]ell-ordered crystals...are difficult to grow because globular protein molecules are large, spherical, or ellipsoidal objects with irregular surfaces, and it is impossible to pack them into a crystal without forming large holes or channels between the individual molecules" (p. 374). See also the teachings of Kierzek et al. and Buts et al. as noted above.

The amount of direction provided by the inventor; The existence of working examples:

In this case, the specification and prior art fail to enable even a single crystal of a polypeptide of claims 1-2 and 15 for reasons that follow.

The quantity of experimentation needed to make or use the invention based on the

content of the disclosure: While methods of protein crystallization were known in the art at the time of the invention, it was *not* routine in the art to crystallize any number

proteins as encompassed by the claims optionally complexed with any ligand under any crystallization conditions to make all crystals as broadly encompassed by the claims, particularly in view of the lack of guidance and working examples provided by the specification.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of required experimentation, it is the examiner's position that undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

[13] Claims 28, 30, and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is the examiner's position that undue experimentation is required for a skilled artisan to make and/or use the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). MPEP 2164.04 states, "[w]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection" and that "[t]he language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims." Accordingly, the Factors most relevant to the instant rejection are addressed in detail below.

Breadth of the claims: The crystals of claims 28 and 30 although reciting space group and unit cell dimensions, encompass a genus of crystals of polypeptides "having the amino acid sequence...", wherein "having" has been interpreted as being inclusive and open-ended and thus encompasses crystals of SEQ ID NO:10 or 6 comprising any additional amino acid sequence at the N- and/or C-termini. However, even assuming

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arguendo the claims were limited to a crystal of SEQ ID NO:10 or 6 and not a crystal of a protein comprising SEQ ID NO:10 or 6, the claims would be rejected for reasons that follow.

The state of the prior art; The level of one of ordinary skill; The level of predictability in the art: The state of the art at the time of the invention acknowledges a high level of unpredictability for making the full scope of claimed crystals. For example, the reference of Branden et al. ("Introduction to Protein Structure Second Edition", Garland Publishing Inc., New York, 1999; cited in the Office action mailed on 8/26/05) teaches that "[c]rystallization is usually quite difficult to achieve" (p. 375). In view of the use of the claimed crystal for generating a three-dimensional structure, it is noted that the claimed crystals should be of diffraction quality, having a well-ordered structure. Branden et al. teaches that "[w]ell-ordered crystals...are difficult to grow because globular protein molecules are large, spherical, or ellipsoidal objects with irregular surfaces, and it is impossible to pack them into a crystal without forming large holes or channels between the individual molecules" (p. 374). See also Kierzek et al. (cited in the Office action mailed on 8/8/06), which teaches "each protein crystallizes under a unique set of conditions that cannot be predicted from easily measurable physico-chemical properties...crystallization conditions must be empirically established for each protein to be crystallized" (p. 2, left column, top) and that protein crystallization is sensitive even to small changes in parameters such as concentrations of additives, temperature, and pH (p. 2, right column, top).

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The amount of direction provided by the inventor; The existence of working examples:

While the specification discloses two crystallization methods to achieve a crystal of the purified polypeptide of SEQ ID NO:10 co-crystallized with SCH549128 having the space group symmetry $P2_12_12_1$ and the unit cell dimensions of $a=37.999 \text{ \AA}$, $b=45.333 \text{ \AA}$, $c=63.999 \text{ \AA}$, $\alpha=\beta=\gamma=90^\circ$ (specification at pp. 45-46) and a crystal of SEQ ID NO:6 (Hdm2 Y76H) co-crystallized with $\text{Ac-}^{60}\text{ClWAC}_{30}\text{E}$ having space group symmetry $P2_12_12_1$ and the unit cell dimensions of $a=41.1 \text{ \AA}$, $b=42.7 \text{ \AA}$, $c=53.777 \text{ \AA}$, $\alpha=\beta=\gamma=90^\circ$ (specification at p 63), the specification lacks critical disclosure that would enable a skilled artisan to make the disclosed crystal. Regarding the crystal of SEQ ID NO:10, it is noted that the specification discloses the polypeptide was co-crystallized with SCH549128, however, the structure of SCH549128 is not disclosed in the specification and it is unclear as to whether this compound was known in the prior art at the time of the invention such that a skilled artisan could obtain the compound of "SCH594128." It is noted that the crystal of claim 28 is a crystal of SEQ ID NO:10 and $\text{Ac-}^{60}\text{ClWAC}_{30}\text{E}$, however, the specification does not appear to disclose a method for making such a crystal. Regarding the crystal of SEQ ID NO:6, it is noted that the specification fails to disclose the concentration of $\text{Ac-}^{60}\text{ClWAC}_{30}\text{E}$ used in the crystallization method, which is critical for repeating a crystallization method. See, e.g., Kierzek et al. at p. 2, right column.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of required experimentation, it is the examiner's position

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that undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

RESPONSE TO ARGUMENT: Addressing the crystal of claims 28 and 30, applicant argues the rejection is obviated in view of the amendment to recite a specific polypeptide, space group and unit cell dimensions of the claimed crystal. Applicant argues Examples 1-3 of the specification teach how to generate and crystallize the HDM2 polypeptides and structural characteristics of the claimed crystals are disclosed at pp. 46 and 63. However, at least for the reasons noted above, the crystals of claims 28 and 30 are not enabled by the specification.

Conclusion

[14] Status of the claims:

- Claims 1-2, 14-15, 28, 30, and 34-35 are pending.
- Claim 14 appears to be in condition for allowance.


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- Claims 1-2, 15, 28, 30, and 34-35 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656